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Sammy G. Duncan Jr. Ph.D. Type or print name ____

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

SUN ET AL.

APPLICATION NO: 10/780,415

FILED: FEBRUARY 17, 2004

FOR: BICYCLIC MODULATORS OF ANDROGEN RECEPTOR

FUNCTION

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INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is being filed within three months of the filing date of the application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-3880.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Some of the listed references are of record in parent Application No. 10/438,722 filed May 15, 2003, and copies are available therein. However, applicants are willing to send copies of any or all of these references at the Examiner's request.

Some of the listed references were cited in a search report in a corresponding PCT International application. Copies of these references and the search report are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Sammy G. Duncar Jr. Ph.D.

Attorney for Applicants Reg. No. 46,675

Bristol-Myers Squibb Company Patent Department P.O. Box 4000 Princeton, NJ 08543-4000 (609) 252-6270

Date:

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

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ATTY. DOCKET NO. LA0087A CIP APPLICATION NO. 10/780,415 APPLICANT SUN ET AL. FILING DATE FEBRUARY 17, 2004

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	3,239,345	3/8/66	Hodge et al.			
	AB	4,036,979	7/19/77	Asato			
	AC	4,411,890	10/25/83	Momany			
	AD	5,179,080	1/12/93	Rothkopf			
	AE	5,488,064	1/30/96	Sher			
	AF	5,491,134	2/13/96	Sher et al.			
	AG	5,541,204	7/30/96	Sher et al.			
	АН	5,612,359	3/18/97	Murugesan			
	Al	5,688,808	11/18/97	Jones et al.			
	AJ	5,688,810	11/18/97	Jones et al.			
	AK	5,693,646	12/2/97	Jones et al.			
	AL	5,693,647	12/2/97	Jones et al.			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRAN YES	SLATION NO
 AM	WO 89/07110	8/10/89	PCT				
AN	WO 89/07111	8/10/89	PCT				
AO	WO 93/04081	3/4/93	PCT				
AP	WO 96/19458	6/27/96	PCT				
AQ	WO 97/19086	5/29/97	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AR	Banz, W.J. et al., "Effects of Soy Protein and Soy Phytoestrogens on Symptoms Associated with Cardiovascular Disease in Rats", Journal of Medicinal Food, Vol. 2, Nos. 3-4, pp. 271-273 (1999)
 AS	Beyler, A.L. et al., "Methods for Evaluating Anabolic and Catabolic Agents in Laboratory Animals", Journal of the American Medical Women's Association, Vol. 23, No. 8, pp. 708-721 (1968)
AT	Boris, A. et al., "Comparative Androgenic, Myotrophic and Antigonadotrophic Properties of Some Anabolic Steroids", Steroids, Vol. 15, pp. 61-71 (1970)

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DATE CONSIDERED

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Group

			U.S. I	PATENT DOCUMENTS			 	
EXAMINE R INITIAL		DOCUMENT NUMBER	DATE	NAME	CL	ASS SUBC	ASS	FILING DATE
	2AA	5,696,127	12/9/97	Jones et al.				-
	2AB	5,696,130	12/9/97	Jones et al.			ľ	
	2AC	5,696,133	12/9/97	Jones et al.				
	2AD	5,770,615	6/23/98	Cheng et al.				
	2AE	5,776,983	7/7/98	Washburn et al.				,
	2AF	6,011,029	1/4/00	Ding et al.				
	2AG	6,040,321	3/21/00	Kim et al.				
	2AH	6,043,265	3/28/00	Murugesan et al.				
	2AI	6,184,231	2/6/01	Hewawasam et al.				
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		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRAN	NSLATION NO
	2AM	WO 97/21993	6/19/97	PCT				
	2AN	WO 97/30992	8/28/97	PCT				
	2AO	WO 97/49709	12/31/97	PCT				
	2AP	WO 98/22461	5/28/98	PCT				
	2AQ	WO 98/25929	6/18/98	PCT				
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	2AR	Bourguet, W. et al., "C RXR-α", Nature, Vol.		ture of the ligand-binding dom 7-382 (1995)	nain of the h	uman nuclea	ar rece	ptor
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	2AT			ication of Prodrugs", A Textboubl., Krogsgaard-Larsen, P. a				
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLAS S	TRAN YES	SLATION NO
	3AA	WO 98/38192	9/3/98	PCT				
	3AB	WO 98/54966	12/10/98	PCT				
-	3AC	WO 99/00353	1/7/99	PCT				
	3AD	WO 99/01124	1/14/99	PCT				
	3AE	WO 99/02224	1/21/99	PCT				
	3AF	WO 99/02514	1/21/99	PCT				
	3AG	WO 99/03848	1/28/99	PCT				
	3AH	WO 99/07692	2/18/99	PCT				
	3AI	WO 99/24416	5/20/99	PCT				
	3AJ	WO 99/27890	6/10/99	PCT				
	3AK	WO 99/28324	6/10/99	PCT .				
	3AL	WO 99/43653	9/2/99	PCT				
	3AM	WO 99/54318	10/28/99	PCT				
	3AN	WO 99/54319	10/28/99	PCT				
	3AO	WO 99/54330	10/28/99	PCT				
	3AP	WO 99/65913	12/23/99	PCT				
	3AQ	WO 99/67252	12/29/99	PCT .				
	3AR	WO 99/67253	12/29/99	PCT				
	3AS	WO 00/00485	1/6/00	PCT				
	3AT	WO 00/01389	1/13/00	PCT				
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Group

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

4AA	Bundgaard, H., ed., Design of Prodrugs, Elsevier Science Publishers B.V., publ., (table of contents) (1985)
444	
4AE	Chalepakis, G. et al., "Differential Gene Activation by Glucocorticoids and Progestins Through the Hormone Regulatory Element of Mouse Mammary Tumor Virus", Cell, Vol. 53, pp. 371-382 (1988)
4A0	Delaisi, C. et al., "RU54115, A Tight-Binding Aromatase Inhibitor Potentially Useful for the Treatment of Breast Cancer", J. Steroid Biochem. Molec. Biol., Vol. 41, No. 3-8, pp. 773-777 (1992)
4A[Edwards, J.P. et al., "Nonsteroidal Androgen Receptor Agonists Based on 4-(Trifluoromethyl)-2 <i>H</i> -Pyrano[3,2- <i>g</i>]Quinolin-2-One", Bioorganic & Medicinal Chemistry Letters, Vol. 9, pp. 1003-1008 (1999)
4AE	Evans, R.M., "The Steroid and Thyroid Hormone Receptor Superfamily", Science, Vol. 240, pp.
4AF	Gori, Z. et al., "La Ipertrofia Da Testosterone Del Muscolo Elevatore Dell'ano Di Ratto Castrato. – I) Dati Quantitativi", BollSoc. Ital. Biol. Sper., Vol. 42, 1596-1599 (1966)
4A0	Gori, Z. et al., "La Ipertrofia Da Testosterone Del Muscolo Elevatore Dell'ano Di Ratto Castrato. – II) Osservazioni Al Microscopio Elettronico", BollSoc. Ital. Biol. Sper., Vol. 42, 1600-1601 (1966)
4Al	Grese, T.A. et al., "Molecular determinants of tissue selectivity in estrogen receptor modulators", Proc. Natl. Acad. Sci. USA, Vol. 94, pp. 14105-14110 (1997)
4AI	Hamann, L.G. et al., "Discovery of a Potent, Orally Active, Nonsteroidal Androgen Receptor Agonist: 4-Ethyl-1,2,3,4-tetrahydro-6-(trifluoromethyl)-8-pyridono[5,6-g]-quinoline (LG121071)", J. Med. Chem., Vol. 42, pp. 210-212 (1999)
4A.	Hamann, L.G. et al, "Synthesis and Biological Activity of a Novel Series of Nonsteroidal, Peripherally Selective Androgen Receptor Antagonists Derived from 1,2-Dihydropyridono [5,6-g] quinolines", J. Med. Chem., Vol. 41, pp. 623-639 (1998)
4AI	Heiser, W.C., "Optimizing Electroporation Conditions for the Transformation of Mammalian Cells",
4AI	Hempstock, J. et al., "Inhibition of Growth of Primary Human Prostate Cells by Phytoestrogens", Journal of Medicinal Food, Vol. 2, Nos. 3-4, pp. 243-246 (1999)
4AI	Hershberger, L.G. et al., "Myotrophic Activity of 19-Nortestosterone and Other Steroids Determined by Modified Levator Ani Muscle Method", P.S.E.B.M., Vol. 83, pp. 175-180 (1953)
4A!	Hiraoka, D. et al., "Inhibitory and Stimulatory Effects of Glucocorticoid on Androgen-induced Growth of Murine Shionogi Carcinoma 115 <i>in Vivo</i> and in Cell Culture", Cancer Research, Vol. 47, pp. 6560-6564 (1987)
EXAMINER	DATE CONSIDERED

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Group

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

5AN	Smigel, K., "Breast Cancer Prevention Trial Shows Major Benefit, Some Risk", Journal of the National Cancer Institute, Vol. 90, No. 9, pp. 647-648 (1998)
5AM	Shiau, A.K. et al., "The Structural Basis of Estrogen Receptor/Coactivator Recognition and the Antagonism of This Interaction by Tamoxifen", Cell, Vol. 95, pp. 927-937 (1998)
5AL	Schuur, E.R. et al., "Prostate-Specific Antigen Expression Is Regulated by an Upstream Enhancer", The Journal of Biological Chemistry, Vol. 271, No. 12, pp. 7043-7051 (1996)
5AK	Rodbard, D., "Chapter 3: Mathematics and Statistics of Ligand Assays: An Illustrated Guide", Ligand Assay, Masson Publishing USA, Inc., publ., J. Langan et al., eds, pp. 45-101 (1981)
5AJ	Regal, J.F. et al., "Dietary Phytoestrogens Have Anti-Inflammatory Activity in a Guinea Pig Model of Asthma", P.S.E.B.M., Vol. 223, pp. 372-378 (2000)
5AI	Quella, S.K. et al., "Evaluation of Soy Phytoestrogens for the Treatment of Hot Flashes in Breast Cancer Survivors: A North Central Cancer Treatment Group Trial", Journal of Clinical Oncology, Vol. 18, No. 5, pp. 1068-1074 (2000)
5AH	Okuda, Y. et al., "Testosterone Dependant Regulation of the Enzymes Involved in DNA Synthesis in the Rat Ventral Prostate", The Journal of Urology, Vol. 145, pp. 188-191 (1991)
5AG	Neri, R. et al., "A Biological Profile of a Nonsteroidal Antiandrogen, SCH 13521 (4'-Nitro-3'-Trifluoromethylisobutyranilide)", Endo, Vol. 91, No. 2, pp. 427-437 (1972)
5AF	Navone, N.M. et al., "Establishment of Two Human Prostate Cancer Cell Lines Derived from a Single Bone Metastasis", Clinical Cancer Research, Vol. 3, pp. 2493-2500 (1997)
5AE	Minesita, T. et al., "An Androgen-dependent Mouse Mammary Tumor", Cancer Research, Vol. 25, pp. 1168-1175 (1965)
5AD	Milata, V. et al., "Simple and Convenient Procedure for the Preparation of 1-methyl-4-nitrobenzimidazole", Org. Prep. Proced. Int., Vol. 25, No. 6, pp. 703-704 (1993)
5AC	Kakigami, T. et al., "Synthesis and Structure-Activity Relationship of 3-Substituted Benzamide, Benzo[b]furan-7-carboxamide, 2,3-Dihydrobenzo[b]furan-7-carboxamide, etc.", Chem. Pharm. Bull., Vol. 46, No.1, pp. 42-52 (1998)
5AB	Johannsson, G. et al., "Growth Hormone Treatment of Abdominally Obese Men Reduces Abdominal Fat Mass, Improves Glucose and Lipoprotein Metabolism, and Reduces Diastolic Blood Pressure", Journal of Clinical Endocrinology and Metabolism, Vol. 82, No. 3, pp. 727-734 (1997)
5AA	Imakura, Y. et al., "Regioselective Cleavage Reaction of the Aromatic Methylenedioxy Ring. V. Cleavage with Sodium Alkoxides-Alcohols, Potassium <i>tert</i> -Butoxide-Alcohols, Dimsyl Anion-Methyl Alcohol, Metallic Sodium-Alcohols, etc., Chem. Pharm. Bull. Vol. 40, No. 7, pp. 1691-1696 (1992)

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

6AA	Suzuki, T. et al., "Effects of Antiandrogens on Growth of Androgen-Dependent Mouse Mammary Tumor (Shionogi Carcinoma 115) <i>In Vivo</i> and <i>In Vitro</i> ", J. Steroid Biochem. Molec. Biol., Vol. 37, No. 4, pp. 559-567 (1990)
6AB	Tanenbaum, D.M. et al., "Crystallographic comparison of the estrogen and progesterone receptor's ligand binding domains", Proc. Natl. Acad. Sci. USA, Vol. 95, pp. 5998-6003 (1998)
6AC	Vegeto, E. et al., "The Mechanism of RU486 Antagonism is Dependent on the Conformation of the Carboxy-Terminal Tail of the Human Progesterone Receptor", Cell, Vol. 69, pp. 703-713 (1992)
6AD	Venable, J.H., "Constant Cell Populations in Normal, Testosterone-Deprived and Testosterone-stimulated Levator Ani Muscles", Am. J. Anat., Vol. 119, pp. 263-270 (1966)
6AE	Wermuth, C.G. et al., "Designing Prodrugs and Bioprecursors I: Carrier Prodrugs", The Practice of Medicinal Chemistry, Academic Press, publ., Wermuth, C.G., ed., pp. 671-696 (1996)
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	7AA	4,959,361	9/25/90	Walser				
	7AB	5,693,646	12/2/97	Jones et al.				
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